21 CFR Part 806:
Medical Devices; Reports of Corrections and Removals

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Recall Reporting Requirements

- Objective
  - To review the requirements for reporting medical device corrections and removals to FDA.

Contents

- Scope of 21 CFR 806
- When to Report
- Who must Report
- Why Reporting is required
- What must be Reported
- How to Report
- Additional Questions
  - Expansion of Corrections and Removals
  - Liability
  - Records
  - Public Disclosure

Requirements under 21 CFR 806

- 21 CFR 806.1 - Scope
  - Section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) requires device manufacturers and importers to report promptly (**within 10 working days of initiation**) to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals,

Requirements under 21 CFR 806

- 21 CFR 806.1 cont'd
  - and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

When Do We Have to Report a Correction or Removal to FDA?

- 21 CFR 806.10(b)
  - The manufacturer or importer shall submit any required report within 10-working (business) days of initiating such correction or removal.

WITHIN 10 BUSINESS DAYS

Who Must Report Corrections and Removals to FDA?

- All Manufacturers and Importers are required to report corrections and removals to FDA.

Who Must Report Corrections and Removals to FDA?

- Manufacturer –

  Any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:

  (1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer; or

Who Must Report Corrections and Removals to FDA?

- Manufacturer –

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or…

Who Must Report Corrections and Removals to FDA?

- **Manufacturer** –

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

Who Must Report Corrections and Removals to FDA?

- Importer –

  For the purposes of 21 CFR 806, an importer is any person who imports a medical device into the United States.

Who Must Report Corrections and Removals to FDA?

- 21 CFR 806.10(a)
  - Each device manufacturer or importer shall submit a written report to your FDA district office of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:

Who Must Report Corrections and Removals to FDA?

- 21 CFR 806.10(a)(1) and (a)(2):
  1. To reduce a risk to health posed by the device; or
  2. To remedy a violation of the act caused by the device which may present a risk to health

What Must We Include in the Report?

1. Correction or Removal Report Number
2. Manufacturer or Importer Information
3. Device Identification
4. Marketing Status
5. Model
6. Manufacturer Information
7. Event Description
8. Illnesses or Injuries

What Must We Include in the Report?

6. Quantities
7. Date of Manufacture and Distribution
8. Consignees
9. Communications
10. Statement if missing any above information

1. Report Number

- 21 CFR 806.10(C)(1)
  - The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R".

1. Report Number

- Report Numbers must be in this format:

1234567-MM/DD/YYYY-001-R

Registration # Date Report # C or R

C = Correction
R = Removal

1. Report Number

- If your firm does not have a Registration Number, enter seven zeros in place of the Registration Number, like this:

0000000-MM/DD/YYYY-001-R

1. Report Number

- If your firm submits more than one report to FDA, change the report number to reflect how many reports have been submitted, like this:

  Removal 1 – 1234567-MM/DD/YYYY-001-R

  Removal 2 – 1234567-MM/DD/YYYY-002-R

  Correction 1 – 1234567-MM/DD/YYYY-001-C

  Correction 2 – 1234567-MM/DD/YYYY-002-C

2. Manufacturer or Importer Information

- 21 CFR 806.10(C)(2)
  - The report should contain the name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.

2. Manufacturer or Importer Information

- Like this:

  Device Manufacturer, Inc
  123 Main St
  Anytown, CA 90210
  (949) 555-1212

  Firm Representative:
  Jane Smith, Title
  123 Main St
  Anytown, CA 90210
  (949) 555-1212 x 123

3. Device Identification

- 21 CFR 806.10(C)(3)
  - The brand name and the common name, classification name, or usual name of the device and the intended use of the device.

3. Device Identification

- Be very specific with device name.

This is not acceptable:
Name of Device:
Pump, White

This is acceptable
Name of Device: XYZ Dandy Pump
Pump, Infusion, Implanted, Programmable

3. Device Identification

- Be very specific with the Intended Use. Reflect the FDA cleared/approved Intended Use.

This is <u>not</u> acceptable:

Pumps fluid

This <u>is</u> acceptable:

Intended for use in parenteral, enteral, and epidural therapies and the administration of whole blood and blood products.

4. Marketing Status of Device

- 21 CFR 806.10(C)(4)
  - The report should contain the marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a pre-amendments device, and the device listing number.

    For Example:
    510(k) #: K111234
    PMA #: P111234

5. Model

- 21 CFR 806.10(C)(5)
  - The report should contain the model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

6. Manufacturer's Name

- 21 CFR 806.10(C)(6)
  - The report should contain the manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.

    For example, a firm may be manufacturing at a different site than the site reporting to FDA. Make it clear in the report who is recalling and who is manufacturing

6. Manufacturer's Name

For Example:

Recalling Firm
Device Recaller, Inc
123 Main St
Anytown, CA 90210
(949) 555-1212

Manufacturer
Device Manufacturer, Inc
123 Stone Ave
Devicetown, FL 33756
(800) 555-1212

7. Event Description

- 21 CFR 806.10(C)(7)
  - The report should contain a description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.
  - Include as much relevant information as possible, be clear in terms of what has been done as well as what will be done.

8. Illnesses or Injuries

- 21 CFR 806.10(C)(8)
  - The report should contain information about any illness or injuries associated with the use of the device. If applicable, identify any Medical Device Reports (MDRs) submitted to FDA for these illnesses or injuries.

9. Quantity of Devices

- 21 CFR 806.10(C)(9)
  - The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.

9. Quantity of Devices

For Example:

Total Qty Manufactured: 1,000 Pumps

- Lot 1 – 250
- Lot 2 – 250
- Lot 3 – 250
- Lot 4 – 250

Please also include the number distributed:

Total Qty Distributed: Lots 1 and 2 = 500 Pumps

10. Date of Manufacture or Distribution

- 21 CFR 806.10(C)(10)
  - The report should contain the date of manufacture or distribution and the device's expiration date or expected life.

    For Example:

    Manufactured 01/01/2013 – 04/01/2013

    Expiration date – 4 years from date of manufacture

11. Consignees

- 21 CFR 806.10(C)(11)
  - Your report should contain the names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee

    NOTE: This data should be accurate since FDA may contact these consignees to determine your recall effectiveness.

12. Communications

- 21 CFR 806.10(C)(12)
  - Your report should contain a copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.

    NOTE: If the recall is potentially a Class I Recall, contact FDA District Recall Coordinator as soon as possible to provide your report and customer notification strategy/letter.

13. Missing Information?

- 21 CFR 806.10(C)(13)
  - If any required information is not immediately available, you should provide a statement to FDA as to why it is not available and when it will be submitted.

NOTE: FDA takes recalls very seriously and will follow up with firms submitting incomplete information; possibly taking Regulatory Actions against the firm if necessary. These actions may include Warning Letters, Untitled Letters, Civil Money Penalties, etc.

Requirements under 21 CFR 806

- 21 CFR 806.10(f)
  - No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 – Medical Device Reporting or 1004 – Repurchase, Repairs, or Replacement of Electronic Products.

How do We Report a Correction or Removal to FDA?

- 21 CFR 7.46
  - You are requested to report corrections or removals to your FDA District Recall Coordinator as soon as possible.
- 21 CFR 806.10(b)
  - Remember, you are required to report within 10 business days after initiating such correction or removal.

- You may find your recall coordinator here:

www.fda.gov/
Safety/Recalls/IndustryGuidance/ucm129334.htm

Failure to Comply

- SEC. 502.(t) (21 U.S.C. 352)
  - A device shall be deemed to be misbranded –
    - If it is a device and there was a failure or refusal
      - to comply with any requirement prescribed under section 518 – [Notification],
      - to furnish any material or information required by or under section 519 – [General Rule of Records and Reports on Devices] – or
      - to comply with a requirement under section 522 – [Postmarket Surveillance].

Additional Questions

- Expansion of correction or removal
- Liability
- Records
- Public Disclosure

What if We Expand the Correction or Removal?

- If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device……

What if We Expand the Correction or Removal?

- .....the manufacturer or importer shall within 10-working (business) days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number.

What if We Expand the Correction or Removal?

- Your report for the expansion of the original recall should contain:

1. The original report number
2. All contact information for the manufacturer or importer as required under 21 CFR 806.10(c)(2)
3. Any other information that differs from the original report

Are We Admitting Liability?

- A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury.

Are We Admitting Liability?

- A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.

Exemptions from 21 CFR 806 Requirements

- 21 CFR 806.1 cont'd
  - There are certain actions which are exempt from the Reporting requirements under 806

Exemptions from 21 CFR 806 Requirements

- Exemptions
  1. Changes which improve quality but do not reduce a risk to health or remedy a violation
  2. Market Withdrawals
  3. Routine Servicing
  4. Stock Recoveries

Exemptions from 21 CFR 806 Requirements

- Exemptions
  - Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device

Exemptions from 21 CFR 806 Requirements

- Exemptions
  - Market Withdrawals -

    A Market Withdrawal is a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves no violation of the act, e.g., normal stock rotation practices.

Exemptions from 21 CFR 806 Requirements

- Exemptions
  - Routine Servicing -

    Any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.

Exemptions from 21 CFR 806 Requirements

- Exemptions
  - Stock Recoveries -

    The correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

Exemptions from 21 CFR 806 Requirements

- IF IN DOUBT –

ASK YOUR DISTRICT RECALL COORDINATOR (DRC)

If We Did Not Need to Report our Correction or Removal, What Records Do We Keep?

- Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under 806.10 shall keep a record of such correction or removal.

What Should the Records Contain?

- Records of corrections and removals not required to be reported to FDA under 806.10 shall contain the following information:

1. The brand name, common or usual name, classification, and product code if known, and the intended use of the device

What Should the Records Contain?

2. The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number

3. A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

What Should the Records Contain?

4. Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any follow-ups, and be reviewed and evaluated by a designated person.
   - The justification may include a root cause analysis

5. A copy of all communications regarding the correction or removal.

How Long Should We Keep the Records?

- The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device.

- Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer or importer of the device and maintained for the required period of time

FDA Access to Records

- Each device manufacturer or importer required under this part (21 CFR 806) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

FDA Access to Records

- It is imperative that you keep accurate records of any correction or removal undertaken by your firm.

- FDA can and may inspect these records.

Will FDA Make Our Report Public?

- Any report submitted under this part is available for public disclosure in accordance with part 20, Chapter 1 of Title 21 of the Code of Federal Regulations.

Will FDA Make Our Report Public?

- Before public disclosure of a report, FDA will delete from the report:

1. Any information that constitutes trade secret or confidential commercial or financial information under 20.61 of this chapter; and

Will FDA Make Our Report Public?

2. Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under 20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under 20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient who requests a report all the information in the report concerning that patient

Will FDA Make Our Report Public?

- FDA has an obligation to protect the public health by providing to consumers accurate and timely information which may negatively impact their health.

In Summary

- In summary, the following topics were presented:
  - Who must report corrections and removals
  - The requirements under Title 21 of the Code of Federal Regulations, Part 806
  - Information regarding the contents of an 806 Report
  - A web link to find the FDA District Recall Coordinator to whom you should send your 806 reports

Thank You

If you have further questions regarding reporting requirements, you may contact:

- FDA District Recall Coordinator

www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

or

CDRH-Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

- **1-800-638-2041**
- **301-796-7100**
- **dsmica@fda.hhs.gov**